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DATE: 6/6/16

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

C 3-4 Anterior Cervical Fusion

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

The reviewer is a Neurological Surgeon with over 23 years of experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Overturned (Disagree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male with neck and shoulder pain s/p picking up a heavy bag from the floor to place it in his truck XX/XX/XX.

XX/XX/XX: PT Evaluation: 1. Trapezius strain 2. Strain of left trapezius muscle 3. Left shoulder strain 4. Cervicalgia 5. Acute pain. Therapy Assessment: Patient assessment is consistent with the diagnosis above. Impairment list: AROM, pain, muscle performance and joint mobility. The patient tolerated the current treatment well with no adverse reaction. Prognosis: The patient is a good candidate for therapy intervention and demonstrates good prognosis for improvement. Plan: Patient to be seen 3 times per week for 2 weeks. Therapeutic exercises such as stretching, strengthening, and stabilization to address the impairments of ROM, muscle performance. This will include patient education to address posture, body mechanics and home program. Therapeutic activities such as lifting, pushing, pulling, and carrying to address the ability to perform the identified essential functions. Manual therapy, such as electrical stimulation, ultrasound, and hot/cold to address localized pain and inflammation. Goal: Increase tissue pliability, increase flexibility and decrease pain.

XX/XX/XX: PT: Patient reports that he has left rhomboid pain with cervical movement. Reports he is doing HEP twice daily. Overall progress is slower than expected. Follow-up plan: 8 more visits to decrease pain, increase mobility, progress to 80% lifting, and 100% pushing. He is currently only at 15% goal status, making minimal progress toward goal.

XX/XX/XX: Office Visit. Patient states that he has numbness, aching, and tingling on his left arm. His pain is worse at night and it does wake him from his sleep. He has had physical therapy, but without much relief. He is here for evaluation and treatment. Medications: Ultracet 37.5-325, Zanaflex 4mg, Celebrex 200mg. Patient stands with an

erect posture. Demonstrates a normal gait pattern. There is significant spinal tenderness in the paraspinal muscles. Bilateral straight leg raise was negative. No Waddell sign's present. There is normal sensation to light touch seen in both upper and lower extremities. Normal motor strength. Reflexes in upper and lower extremities are normal at 2 out of 4. There is a negative Spurlings test and negative Lhermitte's sign. The patient demonstrates good ROM with flexion, extension, side bending, and rotation. Spinal motion is with pain. X-ray of cervical spine was performed in the office today. The AP, lateral, flexion and extension views show normal spinal alignment. There is no atlanto-axial or subaxial instability. There is no narrowing of the disc spaces. There is a normal soft tissue pattern and normal radiographic lines. There is a normal appearance to the uncovertebral joints. Plan: At this point I am going to try a conservative approach to treat this patients' pain. I have recommended a PT program for 6-8 weeks consisting of strengthening, ROM, Core isometric exercises, and modalities. I have also recommended starting a Medrol Dose pack, a non-steroidal anti-inflammatory, a muscle relaxer, and pain medication. MRI scan and follow-up in 6 weeks.

XX/XX/XX: Office Visit. He is seen for a follow-up today. His MRI was not done due to insurance denial. He now has pain in his neck and left shoulder, radiating down his arm. His exam today shows that he has 1/4 deep tendon reflex with the left triceps and 2/4 with biceps. There is also some weakness with 4/5 strength testing with biceps and triceps but difficult to tell if it is because of pain or if he is actually having weakness. Plan: I would go ahead and recommend an MRI scan. I will not clear this patient to go back to work again until I have the MRI scan to review.

XX/XX/XX: Office Visit. Patient presents with arm and neck pain. MRI scan was denied again. He states his pain is worse. Plan: MRI scan and EMG.

XX/XX/XX: MRI Scan of Cervical Spine. Impression: 1. Cervical spondylosis with disc desiccation from C2-C7 levels, with minimal disc space narrowing at C3-C4. 2. Central disc protrusion at C3-C4 contacts and slightly indents the ventral surface of the cord, causing mild spinal canal stenosis. The dorsal subarachnoid space is patent. 3. Diffuse disc bulge at C6-C7 indents the ventral thecal sac causing mild spinal canal stenosis. 4. Small central disc protrusion at C5-C6 slightly indents ventral surface of the cord without significant spinal canal stenosis. The dorsal subarachnoid space is patent. 5. Broad-based left foraminal disc protrusion causes moderate left foraminal narrowing at C6-C7. 6. Moderate bilateral foraminal narrowing at C3-C4, mild bilateral foraminal narrowing at C4-C5, mild left foraminal narrowing at C5-C6 levels.

XX/XX/XX: Follow-up. Patient is still having complaints of pain in his neck and radiating into his shoulders. He is having radicular pain from the C4 nerve root because he has disc protrusion at the C3-C4 level causing irritation at C4 nerve root. This is consistent with his pathology on exam, his level of pain. Plan: I have recommended that we go ahead and get him started in some conservative treatment for his neck. I have recommended PT program and also cervical epidural steroid injection and an NSAID. I feel that he can work full time with some restrictions. 6 week recheck. New medication: Mobic 15 mg

XX/XX/XX: Follow-up. He is still complaining of pain in his cervical spine, radiating down into his shoulder. This is consistent to where his pain is on the cervical spine. He has some restriction of motion with flexion, extension, and side bending, more so on the left than right. He has a positive Spurling sign that reproduces pain in the neck and radiating to the shoulder. His epidural injection was denied. Plan: I am resubmitting for injection. I have no other treatment plan for him besides trying an epidural steroid injection at this point. Follow-up after injection.

XX/XX/XX: Follow-up. He continues to have persistent pain with radicular pain stemming from the C3-C4 level causing pain into the upper trapezius region bilaterally. He has cord compression from a cervical disc herniation at C3-4 that is evident on the MRI scan. He states that his pain and symptoms have worsened since his last exam. Physical exam today shows that he has ¾ deep tendon reflexes in the upper extremities. Sensation is grossly intact. He has good strength in upper extremities. He has weakness with shoulder shrug and pain and tenderness again following paracervical and upper trapezius region, bilateral with radicular pain following the C4 nerve root. Plan: With the change and worsening of his symptoms and the fact that he does have a cord compression at the C3-4 level, I have recommended surgery to decompress the cervical cord. This would be for anterior cervical fusion at

level C3-4.

XX/XX/XX: Consult. Plan: Will request CESI @ C3-4 from XXXXXXXX. A UDS collected today to monitor narcotic compliance. A lumbar spine MME was also performed today.

XX/XX/XX: Follow-up. He states that it is getting worse for him. He is having difficulty dealing with the pain. At this point, we had recommended surgery, as this patient has failed conservative therapy according to ODG. He has done a psych evaluation for this and we are waiting for the approval. His physical examination demonstrates that he has a positive Spurling sign with radicular pain down the right arm with parathesias. Plan: We will go ahead and get him set up for some medications until we can get him set up for surgery.

XX/XX/XX: Psychological Evaluation. Summary: The current evaluation reveals an individual who is experiencing functional limitations and persistent pain in his lower back. His levels of depression and anxiety are not at a significant level to contraindicate surgery. However, he might benefit from post-surgical psychological assistance to help deal with the stresses of rehabilitation.

XX/XX/XX: UR. Rationale: Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, this request is non-certified. The records submitted did not contain specific objective findings such as sensorimotor deficits and positive electrodiagnostic studies to support the diagnosis of C3-4 radiculopathy. Also, results of pre-operative psychological evaluation was not submitted for review. As per guidelines, predictors of poor outcome in anterior cervical discectomy and fusion include psychological distress, psychosomatic problems, litigation and workers' compensation. In consideration of the foregoing issues, and the referenced evidence-based practice guidelines, the medical necessity of the requested surgery and inpatient stay has not been established.

XX/XX/XX: UR. Rationale: Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, this request is non-certified. There is no recent comprehensive clinical evaluation of the patient from the treating physician that addresses the proposed surgery considering that the recent report did not contain specific objective findings such as sensorimotor deficits and positive provocative tests to support the diagnosis of C3-4 radiculopathy.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The previous adverse decisions are Overturned and not supported. This patient has persistent disc herniation induced C4 radicular pain despite more than 8 weeks of conservative therapy including PT, NSAIDs, and work restrictions. He has MRI radiographic confirmation of a surgical lesion with central and left sided C3-4 disc herniation. He also has work and home life disturbance due to his refractory left shoulder/arm pain. He meets the ODG criteria for anterior cervical discectomy, fusion and plating as he has refractory severe pain due to cervical nerve root compression confirmed on MRI. He also meets the ODG criteria due to persistent and progressive radicular pain. He has no psychological findings that suggest factors that would make surgery more prone to fail to provide benefit. Therefore, this surgical procedure is considered medically necessary.

PER ODG...

Fusion, anterior cervical	Recommended as an option in combination with anterior cervical discectomy for approved indications, although current evidence is conflicting about the benefit of fusion in general. (See Discectomy/laminectomy/laminoplasty .) Evidence is also conflicting as to whether autograft or allograft is preferable and/or what specific benefits are provided with fixation devices. Many patients have been found to have excellent outcomes while undergoing simple discectomy alone (for one- to two-level procedures), and have also been found to go on to develop spontaneous fusion after an anterior discectomy. (Bertalanffy, 1988) (Savolainen, 1998)
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([Donaldson, 2002](#)) ([Rosenorn, 1983](#)) Cervical fusion for degenerative disease resulting in axial neck pain and no radiculopathy remains controversial and conservative therapy remains the choice if there is no evidence of instability. ([Bambakidis, 2005](#)) Conservative anterior cervical fusion techniques appear to be equally effective compared to techniques using allografts, plates or cages. ([Savolainen, 1998](#)) ([Dowd, 1999](#)) ([Colorado, 2001](#)) ([Fouyas-Cochrane, 2002](#)) ([Goffin, 2003](#)) Cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. ([Wieser, 2007](#)) One meta-analysis found the differences in benefits and harms between the various surgical techniques are small. The surgeon, patient, and health care provider can therefore make the choice of any surgical technique based on experience, preferences, or costs. According to another systematic review, evidence suggests that surgery with or without fusion can be similarly effective, so surgeons should consider each case individually and take into account their own familiarity and expertise with each procedure. ([Verhagen, 2013](#)) ([Yoon, 2013](#)) This evidence was substantiated in a recent Cochrane review that stated that hard evidence for the need for a fusion procedure after discectomy was lacking, as outlined below:

(1) Anterior cervical discectomy compared to anterior cervical discectomy with interbody fusion with a bone graft or substitute: Three of the six randomized controlled studies discussed in the 2004 Cochrane review found no difference between the two techniques and/or that fusion was not necessary. The Cochrane review felt there was conflicting evidence of the relative effectiveness of either procedure. Overall it was noted that patients with discectomy only had shorter hospital stays, and shorter length of operation. There was moderate evidence that pain relief after five to six weeks was higher for the patients who had discectomy with fusion. Return to work was higher early on (five weeks) in the patients with discectomy with fusion, but there was no significant difference at ten weeks. ([Jacobs-Cochrane, 2004](#)) ([Abd-Alrahman, 1999](#)) ([Dowd, 1999](#)) ([Martins, 1976](#)) ([van den Bent, 1996](#)) ([Savolainen, 1998](#)) One disadvantage of fusion appears to be abnormal kinematic strain on adjacent spinal levels. ([Ragab, 2006](#)) ([Eck, 2002](#)) ([Matsunaga, 1999](#)) ([Katsuura, 2001](#)) The advantage of fusion appears to be a decreased rate of kyphosis in the operated segments. ([Yamamoto, 1991](#)) ([Abd-Alrahman, 1999](#))

(2) Fusion with autograft versus allograft: The Cochrane review found limited evidence that the use of autograft provided better pain reduction than animal allograft. It also found that there was no difference between biocompatible osteoconductive polymer or autograft (limited evidence). ([Jacobs-Cochrane, 2004](#)) ([McConnell, 2003](#)) A problem with autograft is morbidity as related to the donor site including infection, prolonged drainage, hematomas, persistent pain and sensory loss. ([Younger, 1989](#)) ([Sawin, 1998](#)) ([Sasso, 2005](#)) Autograft is thought to increase fusion rates with less graft collapse. ([Deutsch, 2007](#)). See [Decompression, myelopathy](#).

(3) Fusion with autograft with plate fixation versus allograft with plate fixation, Single level: A recent retrospective review of patients who received allograft with plate fixation versus autograft with plate fixation at a single level found fusion rates in 100% versus 90.3% respectively. This was not statistically significant. Satisfactory outcomes were noted in all non-union patients. ([Samartzis, 2005](#))

(4) Fusion with different types of autograft: The Cochrane review did not find evidence that a vertebral body graft was superior to an iliac crest graft. ([McGuire, 1994](#))

(5) Fusion with autograft versus fusion with autograft and additional instrumentation:
Plate Fixation: In single-level surgery there is limited evidence that there is any difference between the use of plates and fusion with autograft in terms of union rates. For two-level surgery, there was moderate evidence that there was more improvement in arm pain for patients treated with a plate than for those without a plate. Fusion rate is improved with plating in multi-level surgery. ([Wright, 2007](#)) See [Plate fixation, cervical spine surgery](#).

Cage: Donor site pain may be decreased with the use of a cage rather than a plate, but donor site pain was not presented in a standardized manner. At two years pseudoarthrosis rate has been found to be lower in the fusion group (15%) versus the cage group (44%). A six-year follow-up of the same study group revealed no significant difference in outcome variables between the two treatment groups (both groups had pain relief). In the subgroup of patients with the cage who attained fusion, the overall outcome was better than with fusion alone. Patients treated with cage instrumentation have less segmental kyphosis and better-preserved disc height. This only appears to affect outcome in a positive way in cage patients that achieve fusion (versus cage patients with pseudoarthrosis). ([Poelsson, 2007](#)) ([Varuch, 2002](#)) ([Hacker 2000](#)) See also [Adjacent segment disease/degeneration](#) (fusion).

(6) Fusion with allograft alone versus with allograft and additional instrumentation:

Plate Fixation: Retrospective studies indicate high levels of pseudoarthrosis rates (as high as 20% for one-level and 50% for two-level procedures) using allograft alone. In a recent comparative retrospective study examining fusion rate with plating, successful fusion was achieved in 96% of single-level cases and 91% of two-level procedures. This could be compared to a previous retrospective study by the same authors of non-plated cases that achieved successful fusion in 90% of single-level procedures and 72% of two-level procedures. ([Kaiser, 2002](#)) ([Martin, 1999](#)) See [Plate fixation, cervical spine surgery](#).

Complications:

Collapse of the grafted bone and loss of cervical lordosis: collapse of grafted bone has been found to be less likely in plated groups for patients with multiple-level fusion. Plating has been found to maintain cervical lordosis in both multi-level and one-level procedures. ([Trojanovich, 2002](#)) ([Herrmann, 2004](#)) ([Katsuura, 1996](#)) The significance on outcome of kyphosis or loss of cervical lordosis in terms of prediction of clinical outcome remains under investigation. ([Peolsson, 2004](#)) ([Haden, 2005](#)) ([Poelsson, 2007](#)) ([Hwang, 2007](#)) See also [Laryngoscopy](#) (screening for recurrent laryngeal nerve injury prior to revision ACDF).

Pseudoarthrosis: This is recognized as an etiology of continued cervical pain and unsatisfactory outcome. Treatment options include a revision anterior approach vs. a posterior approach. Regardless of approach, there is a high rate of continued moderate to severe pain even after solid fusion is achieved. ([Kuhns, 2005](#)) ([Mummaneni, 2004](#)) ([Coric, 1997](#))

Anterior versus posterior fusion: In a study based on 932,009 hospital discharges associated with cervical spine surgery, anterior fusions were shown to have a much lower rate of complications compared to posterior fusions, with the overall percent of cases with complications being 2.40% for anterior decompression, 3.44% for anterior fusion, and 10.49% for posterior fusion. ([Wang, 2007](#))

Predictors of outcome of ACDF: Predictors of good outcome include non-smoking, a pre-operative lower pain level, soft disc disease, disease in one level, greater segmental kyphosis pre-operatively, radicular pain without additional neck or lumbar pain, short duration of symptoms, younger age, no use of analgesics, gainful employment, higher preoperative NDI and normal ratings on biopsychosocial tests such as the Distress and Risk Assessment Method (DRAM). Predictors of poor outcomes include non-specific neck pain, psychological distress, psychosomatic problems and poor general health, litigation and workers' compensation. ([Anderson, 2009](#)) ([Peolsson, 2006](#)) ([Peolsson, 2003](#)) Patients who smoke have compromised fusion outcomes. ([Peolsson, 2008](#))

See [Plate fixation, cervical spine surgery](#). See also [Adjacent segment disease/degeneration](#) (fusion) & [Iliac crest donor-site pain treatment](#).

Use of Bone-morphogenetic protein (BMP): FDA informed healthcare professionals of reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine for spinal fusion. The safety and effectiveness of rhBMP in the cervical spine have not been demonstrated, and these products are not

approved for this use. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. ([FDA MedWatch, 2008](#)) Bone-morphogenetic protein was used in approximately 25% of all spinal fusions nationally in 2006, with use associated with more frequent complications for anterior cervical fusions. No differences were seen for lumbar, thoracic, or posterior cervical procedures, but the use of BMP in anterior cervical fusion procedures was associated with a higher rate of complication occurrence (7.09% with BMP vs 4.68% without BMP) with the primary increases seen in wound-related complications (1.22% with vs 0.65% without) and dysphagia or hoarseness (4.35% with vs 2.45% without). ([Cahill-JAMA, 2009](#))

ACDF in workers' comp (WC) patients: The impact of worker's compensation (WC) on outcomes following ACDF is significant. The WC cohort demonstrated lower clinical improvement, reduced 1-year arthrodesis rate (pseudarthrosis rate was 7.6% for WC versus 0.9%), and an increased incidence of revision/reoperations (12.9%) compared with non-WC patients (2.7%). WC patients were associated with 282% higher reimbursement rates than non-WC patients. ([Tabaraee, 2015](#))

For hospital LOS after admission criteria are met, see [Hospital length of stay](#) (LOS).

Criteria for Cervical Fusion – Recommended Indications:

- (1) Acute traumatic spinal injury (fracture or dislocation) resulting in cervical spinal instability.
- (2) Osteomyelitis (bone infection) resulting in vertebral body destruction.
- (3) Primary or metastatic bone tumor resulting in fracture instability or spinal cord compression.
- (4) Cervical nerve root compression verified by diagnostic imaging (i.e., MRI or CT myelogram) and resulting in severe pain OR profound weakness of the extremities.
- (5) Spondylotic myelopathy based on clinical signs and/or symptoms (Clumsiness of hands, urinary urgency, new-onset bowel or bladder incontinence, frequent falls, hyperreflexia, Hoffmann sign, increased tone or spasticity, loss of thenar or hypothenar eminence, gait abnormality or pathologic Babinski sign) and Diagnostic imaging (i.e., MRI or CT myelogram) demonstrating spinal cord compression.
- (6) Spondylotic radiculopathy or nontraumatic instability with All of the following criteria:
 - (a) Significant symptoms that correlate with physical exam findings AND radiologist-interpreted imaging reports.
 - (b) Persistent or progressive radicular pain or weakness secondary to nerve root compression or moderate to severe neck pain, despite 8 weeks conservative therapy with at least 2 of the following:
 - Active pain management with pharmacotherapy that addresses neuropathic pain and other pain sources (e.g., an NSAID, muscle relaxant or tricyclic antidepressant);
 - Medical management with oral steroids or injections;
 - Physical therapy, documented participation in a formal, active physical therapy program as directed by a physiatrist or physical therapist, may include a home exercise program and activity modification, as appropriate.
 - (c) Clinically significant function limitation, resulting in inability or significantly decreased ability to perform normal, daily activities of work or at-home duties.
 - (d) Diagnostic imaging (i.e., MRI or CT myelogram) demonstrates cervical nerve root compression, or Diagnostic imaging by x-ray demonstrates Instability by flexion and extension x-rays; Sagittal plane translation >3mm; OR Sagittal plane translation >20% of vertebral body width; OR Relative sagittal plane angulation >11 degrees.
 - (e) Not recommend repeat surgery at the same level.
 - (f) Tobacco cessation: Because of the high risk of pseudoarthrosis, a smoker anticipating a spinal fusion should adhere to a tobacco-cessation program that results in abstinence from tobacco for at least six weeks prior to surgery.
 - (g) Number of levels: When requesting authorization for cervical fusion of multiple levels,

	<p>each level is subject to the criteria above. Fewer levels are preferred to limit strain on the unfused segments. If there is multi-level degeneration, prefer limiting to no more than three levels. With one level, there is approximately a 80% chance of benefit, for a two-level fusion it drops to around 60%, and for a three-level fusion to around 50%. But not fusing additional levels meeting the criteria, risks having to do future operations.</p> <p>(h) The decision on technique (e.g., autograft versus allograft, instrumentation) should be left to the surgeon.</p>
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A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**